

REMARKS

I. Status of the Claims

Claims 1-20 are pending and, with the withdrawal of the election of species requirement, are under examination and stand rejected under 35 U.S.C. §112, first and second paragraphs. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

II. Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 1-10 and 14-19 are rejected as indefinite under the second paragraph of §112. The term "said cancer cell" is alleged to lack antecedent basis in claim 1. An amendment is provided that addresses the rejection. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

III. Rejection Under 35 U.S.C. §112, First Paragraph

Claims 1 and 5-20 stand rejected as lacking enablement under the first paragraph of §112. The examiner argues that not all therapeutic agents are enabled, in particular nucleic acid constructs. Diagnostic agents, however, are indicated as enabled. Applicants traverse, as explained below.

The examiner addresses the *Wands* factors at the top of page 4 of the office action, and immediately thereafter states that "the guidance presented in the specification with respect to the targeting of therapeutic agents *that are nucleic acid constructs* is minimal, because the specification does not provide working examples demonstrating specific methods of therapy *where an antisense or gene therapy nucleic acid construct* is targeted to a cell or cancer cell, where this targeting results in a therapeutic effect" (emphasis added). At pages 5-6 of the action,

a detailed argument against the enablement of antisense is provided; at pages 6-7, a detailed argument against the enablement of gene therapy is provided.

Applicants traverse this rejection as not well-founded. The present invention is about targeting of agents – *any agents* – to a cancer cell. The examiner, by acknowledging that diagnostic agents are in fact capable of being targeted, acknowledges the underlying enablement of this technology. In attacking gene therapy and antisense, this is not an attack on the enablement of the present invention, but an attack on gene therapy and antisense as a completely distinct field of endeavor. Applicants need not provide a rebuttal that challenges the efficacy of gene therapy or antisense as a general matter – rather, the examiner must explain why the present invention would be expected *not* to work with known examples of successful gene therapy and antisense. As numerous U.S. patents have issued on antisense and gene therapy, it cannot be argued that such endeavors are entirely unworkable.

However, an solely in the interest of advancing the prosecution, the claims have been amended to remove subject matter directed to “nucleic acids constructs” by reciting a series of agents, both diagnostic and therapeutic, which have not been properly challenged. In this regard, it is noted that not a single word of argument is advanced against therapeutic agents *other than nucleic acids*, namely, chemotherapeutics, radiotherapeutics, toxins or cytokines. As such, no *prima facie* case has been established against the enablement of this subject matter, now recited in claim 1, the only independent claim.

Applicants respectfully submit that the claims as presented for reconsideration address the specific enablement concerns advanced by the examiner. As such, reconsideration and withdrawal of the rejection is respectfully requested.

IV. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. The examiner is invited to contact the undersigned attorney at the telephone number listed below with any questions, comments or suggestions relating to the above-referenced patent application.

Respectfully submitted,


Steven N. Highlander
Reg. No. 37,642
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 536-3184

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